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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C
PO BOX 7021
TROY, MI 48007-7021

EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,203	COSENZA, LAWRENCE W.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-10, 12-15, and 41, drawn to a therapeutic delivery system comprising a therapeutic agent which is a gene, and a sacromastigophoric organism containing said therapeutic agent and a lytic factor..

II. Claims 2, 4-10, 13, and 41, drawn to a therapeutic delivery system comprising a therapeutic agent which is a an artificial chromosome, and a sacromastigophoric organism containing said therapeutic agent and a lytic factor.

III. Claims 2, 4-10, 13, and 41, drawn to a therapeutic delivery system comprising a therapeutic agent which is a magnetic species, and a sacromastigophoric organism containing said therapeutic agent and a lytic factor.

IV. Claims 2, 4-10, 13, and 41, drawn to a therapeutic delivery system comprising a therapeutic agent which is a radioactive species, and a sacromastigophoric organism containing said therapeutic agent and a lytic factor.

V. Claims 2, 4-10, 13, and 41, drawn to a therapeutic delivery system comprising a therapeutic agent which is a vitamin, and a sacromastigophoric organism containing said therapeutic agent and a lytic factor.

VI. Claims 2, 4-10, 13, and 41, drawn to a therapeutic delivery system comprising a therapeutic agent which is a nanocrystal, and a sacromastigophoric organism containing said therapeutic agent and a lytic factor.

VII. Claims 2, 4-10, 13, and 41, drawn to a therapeutic delivery system comprising a therapeutic agent which is a drug or prodrug, and a sacromastigophoric organism containing said therapeutic agent and a lytic factor.

VIII. Claims 17-24, and 26-31, drawn to a process for producing a sacromastigophoric organism comprising culturing a sacromastigophoric organism that has been transfected with a construct having a promoter controlling expression of a lytic protein, and a second construct encoding a second promoter and a preselected gene.

IX-XIII. Claims 17-19, and 23-26, drawn to a process for producing a sacromastigophoric organism comprising culturing a sacromastigophoric organism that has been transfected with a construct having a promoter controlling expression of a lytic protein and packaging a non-nucleic acid therapeutic agent in said organism.

Invention X- the non-nucleic acid agent is a magnetic species
Invention XI-the non-nucleic acid agent is a radioactive species
Invention XII-the non-nucleic acid agent is a vitamin
Invention XIII-the non-nucleic acid agent is a nanocrystal
Invention XIV-the non-nucleic acid agent is a drug or prodrug.

XIV. Claims 33-37 and 40, drawn to methods of treating a disease in a host by administering a sacromastigophoric organism transfected with a construct having a promoter controlling expression of a lytic protein and a second construct having a second promoter and a preselected gene, and administering an exogenous species to induce lysis.

XV-XIX. Claims 33-35, and 38-40, drawn to methods of treating a disease in a host by administering a sacromastigophoric organism transfected with a construct having

a promoter controlling expression of a lytic protein, packaging a non-nucleic acid therapeutic agent into the organism prior to administration to the host, and administering an exogenous species to induce lysis.

Invention XV- the non-nucleic acid agent is a magnetic species
Invention XVI-the non-nucleic acid agent is a radioactive species
Invention XVII-the non-nucleic acid agent is a vitamin
Invention XVIII-the non-nucleic acid agent is a nanocrystal
Invention XIX-the non-nucleic acid agent is a drug or prodrug.

Claims 1 and 11 link(s) inventions I-VII; claim 16 links inventions VIII-XIII; and claim 32 links inventions XIV-XIX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 11, or 16, or 32 . Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-VII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each product comprises a therapeutic agent which is materially different in chemical, physical, structural, and functional properties from the others. Further, the mode of operation of each agent is substantially different from each of the others. As such, each product is not an obvious variant of the other and the inventions are not capable of use together. Therefore, it would place an undue burden on the examiner to search and examine all of inventions I-VII together.

Inventions VIII-XIII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the different processes involve the use of method steps which utilize materially different products comprising therapeutic agents with different properties, modes of operation and effects. In addition, note that the methods of inventions IX-XIII involve the step of packaging a non-nucleic acid agent into the organism which is not required for the methods of invention VIII. As such, the methods of producing each product are

not an obvious variant of the others and the inventions are not capable of use together. Therefore, it would place an undue burden on the examiner to search and examine all of inventions VIII-XIII together.

Inventions XV-XIX are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of each invention involve the administration of materially different products comprising therapeutic agents with different properties, modes of operation and effects. As such, each method is not an obvious variant of any of the others and the inventions are not capable of use together. Therefore, it would place an undue burden on the examiner to search and examine all of inventions XV-XIX together.

Invention II and Inventions VIII-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of invention II cannot be used in the methods of inventions XIV-XIX and the methods of making of inventions VIII-XIII cannot be used to make the product of invention II. As such, the search for invention II is completely separate and not coextensive with that for any of the inventions VIII-XIII. Therefore, it would place an undue burden on the examiner to search and examine all of inventions II and VIII-XIX together.

Inventions VIII and XIV are related as process of making and process of using the product of invention I. Inventions IX and XV are related as process of making and process of

using the product of invention III. Inventions X and XVI are related as process of making and process of using the product of invention IV. Inventions XI and XVII are related as process of making and process of using the product of invention V. Inventions XII and XVIII are related as process of making and process of using the product of invention VI. Inventions XIII and XIX are related as process of making and process of using the product of invention VII. The uses as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Invention I and inventions IX-XIII and XV-XIX are unrelated. Inventions III and inventions VIII, X-XIV, XVI-XIX are unrelated. Inventions IV and inventions VIII-IX, XI-XV, XVII-XIX are unrelated. Inventions V and inventions VIII-X, XII-XVI, XIII-XIX are unrelated. Inventions VI and inventions VIII-XI, XIII-XVII, XIX are unrelated. Inventions VII and inventions VIII-XII, XIV-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In each instance, the products of each of invention I and II-VII cannot be used in the methods of indicated inventions and the methods of making of indicated inventions cannot be used to make the products. As such, the searches are not coextensive and it would place an undue burden on the examiner to search and examine all of the indicated inventions together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of lytic factors:

a) Hpr

b) trialysin

c) Bad

d) Bax

The species are independent or distinct because each lytic factor is a unique protein expressed from a unique gene with different structural, chemical, physical, and functional properties. Thus, the search for one lytic factor is not co-extensive with the search for any other and as such it would place an undue burden on the examiner to search and examine all species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims except 26-30 are generic.

This application further contains claims directed to the following patentably distinct species of sacromastigophoric organisms:

a) Trypanosoma

b) Plasmodium

c) Amoeba

d) Giardia

e) Entamoeba

f) Leishmania

The species are independent or distinct because each organism is structurally, chemically, physically, and functionally different. The organisms further infect different types of cells, and cause different diseases. Thus, the search for one organism is not co-extensive with the search for any other and as such it would place an undue burden on the examiner to search and examine all species together

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5, 7-10, 16-17, 20-25, 31-33, and 35-42 are generic.

This application further contains claims directed to the following patentably distinct species of genes:

a) host genes or a polymorph thereof

b) native sacromastigophoric organism genes

c) pathogen genes or a polymorph thereof

d) viral or proviral genes

The species are independent or distinct because each type of gene is derived from a substantially different type of organism. Hosts for sacromastigophoric organisms are mammals, which are entirely different from viruses, pathogens, or organisms such as a trypanosome. The other species of genes are likewise unrelated. Thus, the search for one type of gene is not co-

extensive with the search for any other and as such it would place an undue burden on the examiner to search and examine all species together

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-24, 26-37, and 40-42 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the

USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER